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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0312]

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Certifier Shankley

Animal Feed Safety System: A Comprehensive Risk-Based Safety Program for the Manufacture and Distribution of Animal Feeds; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, we) held a public meeting in Herndon, VA on September 22 and 23, 2003, to discuss the potential development of a comprehensive, risk-based animal feed safety system (AFSS). The AFSS is intended to describe how animal feeds (individual ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and humans consuming food products from animals. During the meeting, we stated we would be keeping the public informed of our progress on this initiative and would be seeking comments and continued participation as we proceed.

To that end, we have placed in FDA's docket for public comment numerous work products of the meeting, along with documents we drafted following the meeting to show our tentative thoughts on an AFSS.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments concerning this document to the Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: George Graber, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6651, FAX 301–594–4512, or e-mail: george.graber@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The public meeting held in Herndon, VA included active participation of people representing consumers, animal feed processors, animal producers and State and other Federal Government agencies. Following the meeting, we placed a number of documents in FDA's docket at http://www.fda.gov/ohrms/ dockets/dockets/dockets.htm. These include a transcript of the meeting, summaries of break out discussion groups, presentations of invited speakers, and a summary of the meeting. We stated our view that an AFSS should be comprehensive and risk-based, and we have since drafted definitions for these terms and placed them in the docket. Likewise, we have created a listing of elements we currently feel would be essential to an AFSS and added them to the docket. As additional material is generated, it will also be posted. We welcome your comments on these materials. For convenience, you may visit FDA's Center for Veterinary Medicine home page at http://www.fda.gov/cvm/ index/animalfeed/animalfeed info.htm#biotechnology, and click on "FDA" Animal Feed Safety System (AFSS) Public Meeting" under the "Additional Information" section for links to documents in FDA's docket.

II. Comments

Interested persons may submit comments to the Division of Dockets

Management (see ADDRESSES) written or electronic comments regarding this
document. Submit a single copy of electronic comments or two paper copies
of any mailed comments, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in
the heading of this document. Received comments may be seen in the Division

of Dockets Management between 9 a.m.and 4 p.m., Monday through Friday. You can also view received comments on the Internet at http://www.fda.gov/ ohrms/dockets/dockets.htm.

Dated: 3/25/67
March 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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